

REMARKS

Applicants' invention relates to biocompatible matrices for the delivery of gases, such as oxygen, and other agents for the treatment of compromised tissues. Applicants respectfully request reconsideration of the present application in view the foregoing amendments and remarks. Claims 1-12, and 21-33 are pending. Claims 1, 7, 9, 12, 21, 24, 29 and 30 have been amended. Support for these claims can be found throughout the specification. No new matter has been added by these amendments.

Rejection of Claims 1-20 under 35 U.S.C. § 102(b) and § 103(a)

The Examiner rejected Claims 1-20 under 35 U.S.C. §102(b) as anticipated by, or in the alternative, under 35 U.S.C. § 103(a) as obvious over, U. S. Patent No. 5,792,090 to Ladin (hereinafter *Ladin*). Applicants note that Claims 1-12 and 21-33 are currently pending and that Claims 13-20 were cancelled in an earlier communication.

The Examiner stated that *Ladin* relates to the healing of surface wounds through the use of an oxygen generating wound dressing. The Examiner found that the wound dressing contains an oxygen permeable membrane that is incapable of, or inefficient in, transmitting ionic substances in solution, such as peroxide ion, hydroxide ion, and heavy metal ions. The Examiner also found that the device, in use, generates oxygen, and that SARAN wrap placed on top of the entire device helps seal in the oxygen, and helps direct the oxygen towards the wound. The Examiner added that since the *Ladin* device is incapable or inefficient for transmitting ionic substances, the device is considered a closed construct.

Applicants respectfully traverse this rejections for the following reasons. *Ladin* does not teach, nor does *Ladin* suggest or render obvious, Applicants' currently pending claims, as amended in this Response. The devices taught by *Ladin* are required to have "a reservoir containing a renewable, nonsustaining chemical oxygen source." See *Ladin*, Col. 5, lines 54-55. Though the reservoir taught in *Ladin* may be found in different forms, such as open-celled foam or sponges, the reservoir is required to contain a chemical that will react when the correct secondary material is added to generate oxygen. No oxygen is present until the

correct secondary material is added to the reservoir to cause the chemical to undergo a chemical change and create oxygen. The correct secondary material is not added until the device is in use. In contrast, Applicants' currently pending claims recite that oxygen is entrapped within the matrix, not a chemical. The teaching in *Ladin* is to provide wound healing devices that have a chemical within a matrix and that oxygen is formed once the device is in place, by the addition of the correct secondary material. Without the addition of the correct secondary material, the matrix of *Ladin* is merely a matrix with a chemical entrapped within a reservoir. Additionally, not just any secondary material can cause the generation of oxygen. The secondary material must be the correct or particular material that reacts with the chemical residing the reservoir of the matrix. Without the correct secondary material, no oxygen will ever be present in the devices taught by *Ladin*.

Furthermore, the teaching of *Ladin*, is that multiple components are necessary in the device to provide the oxygen to a wound surface. See *Ladin*, Col. 3, lines 28-30, wherein the Summary of the Invention teaches that "[t]he subject invention pertains to a multiplayer dressing..." At the least, the *Ladin* devices require an oxygen permeable membrane that is "located exterior" to the reservoir containing the chemical agent that is capable of producing oxygen if the correct secondary material is added. See *Ladin*, Col.5 , lines 51-54. The *Ladin* device further requires an exterior cover of the wound dressing, presumably so that the oxygen generated by the addition of the correct secondary material is not dissipated into the atmosphere above the wound surface. See *Ladin*, Col. 6, lines 30-32. In contrast, Applicants' currently claimed invention provides a matrix that contains oxygen entrapped in closed cells formed in the matrix.

The teachings of *Ladin*, of a device requiring multiple components and multiple layers, and needing at least an oxygen permeable membrane, an exclusion layer, a reservoir containing chemicals and the addition of the correct secondary material do not anticipate Applicants' currently claimed invention of a matrix with oxygen entrapped within closed cells. *Ladin* does not render Applicants' currently claimed invention obvious. The teaching or suggestion of *Ladin* is that a device must be formed with multiple components, so that when the correct secondary material is added to the device, when in place on the wound site,

the secondary material will reach the reservoir and the chemicals will react appropriately and generate the oxygen that then must be transmitted to the wound site through an oxygen permeable membrane. Exclusive materials must be used to prevent the dissipation of the oxygen into the atmosphere above the wound. *Ladin* does not teach or suggest a matrix having oxygen entrapped within closed cells that is placed on a wound site. No secondary material is added to generate oxygen at the wound site for Applicants' matrix.

Ladin does not provide a teaching that anticipates Applicants' currently pending claims nor does *Ladin* provide a disclosure that renders Applicants' currently pending claims obvious. Applicants request that the Examiner withdraw this rejection.

Version to Show Changes Made

Pursuant to 37 C.F.R. §1.121(c)(1)(ii), a version of the rewritten claims, marked up to show all the changes relative to the previous version of the claims, is now set forth with deleted text shown in [brackets] and added text shown in underlining:

1. (Twice Amended) An oxygen-delivery matrix, comprising, a biocompatible matrix, comprising

[wherein the biocompatible matrix comprises] a polymer network, a non-gellable polysaccharide, and oxygen, wherein the oxygen is generated in the matrix in the manufacture of the matrix, creating multiple oxygen-rich, closed cells within the matrix;

and wherein the non-gellable polysaccharide and oxygen are dispersed throughout the polymer network, [, creating an oxygen-rich, closed cell polymer foam]

7. (Amended) The matrix of Claim [5] 6, wherein the decomposition of the peroxide is caused by a catalyst.

9. (Amended) The matrix of Claim 7, wherein the catalyst is a salt of iodide, manganese dioxide[,] or cupric chloride.

12. (Twice Amended) The matrix of Claim 1, wherein the polymer network comprises a natural or synthetic polymer.

21. (Amended) The matrix of Claim 2, wherein the active agent comprises gases, anti-microbial agents, anti-fungal agents, anti-bacterial agents, anti-viral agents, anti-parasitic agents, mycoplasma treatments, growth factors, proteins, nucleic acids, angiogenic factors, anaesthetics, mucopolysaccharides, metals, pharmaceuticals, chemotherapeutic agents, herbicides, growth inhibitors, anti-fungal agents, anti-bacterial agents, anti-viral agents and anti-parasitic agents, [mycoplasma treatments, growth factors, proteins, nucleic acids, angiogenic factors, anaesthetics, mucopolysaccharides, metals,] wound healing agents, growth promoters, indicators of change in the environment, enzymes, nutrients, vitamins, minerals, carbohydrates, fats, fatty acids, nucleosides, nucleotides, amino acids, sera,

antibodies and fragments thereof, lectins, immune stimulants, immune suppressors, coagulation factors, neurochemicals, cellular receptors, antigens, adjuvants and radioactive materials.

24. (Amended) The matrix of Claim 21, wherein the growth factor agents comprise basic fibroblast growth factor, acidic fibroblast growth factor, nerve growth factor, epidermal growth factor, insulin-like growth factors 1 and 2, platelet derived growth factor, tumor angiogenesis factor, vascular endothelial growth factor, corticotropin releasing factor, transforming growth factors α and β , interleukin-8, granulocyte-macrophage colony stimulating [facto] factor, interleukins, and interferons.

29. (Amended) The matrix of Claim 27, wherein the polymer network comprises a natural or synthetic polymer.

30. (Amended) The matrix of Claim 28, wherein the polymer network comprises collagen, gelatin, chondritin, calmodulin, cellulose, agar, agarose, animal hide, hyaluronic acid, dextran, alginate, polylysine, resorbable polymers, polyacrylamide, polymethacrylate, polyacrylate, polybuterate, polyurethane foam, polyether, silastic, silicone elastomer, rubber, nylon, vinyl and cross-linked dextran.

CONCLUSION

The foregoing is a complete response to the Office Action mailed July 15, 2002. Applicants respectfully submit that Claims 1-12, and 21-33 are patentable. Early and favorable consideration is solicited.

No fees are believed due; however, the Commissioner is hereby authorized to charge any fees that may be required, or credit any overpayment, to Deposit Account No. 11-0855.

If Examiner believes there are other issues that can be resolved by a telephone interview, or there are any informalities that remain in the application which may be corrected by the Examiner's amendment, a telephone call to the undersigned attorney at (404) 745-2426 is respectfully solicited.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Mary A. Merchant', with a stylized flourish at the end.

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